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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,451

03/09/2004

Adnan Badwan

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FITCH EVEN TABIN AND FLANNERY  
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CHICAGO, IL 60603-3406

EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

4173

MAIL DATE

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10/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/796,451

Applicant(s)

BADWAN ET AL.

Examiner

Tristan J. Mahyera

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 07/12/2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I in the reply filed on 08/07/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).
2. Claims 14 and 15 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Claims 1 – 13 are examined on the merits.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are the only part of the claimed invention. See MPEP § 2173.05(d). The phrase "consisting of...inorganic acids such as..." and the phrase "consisting of...organic acids such as..." is not defined by the

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claim nor does the specification provide a standard for ascertaining the requisite meets and bounds, thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "such as" typically indicates only the following specific compounds. However, the phrase "consisting of...inorganic acids" or "consisting of...organic acids" is open to the full genus of inorganic or organic acids. The phrase "consisting of...inorganic acids" or "consisting of...organic acids" is controverted by the term "such as" which implies only the following list of acids is permitted. Further, the extent of variance permitted by "such as" is unclear in the context. Thus the interpretation of the phrase "such as" in this context is unclear.

7. Regarding claim 8, the phrase "at least about 65% of norfloxacin" renders the claim indefinite because it simultaneously claims two different ranges. The phrase "at least about 65%" is not defined by the claim nor does the specification provide a standard for ascertaining the requisite meets and bounds, thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "at least" typically indicates a minimum point. However, the phrase "at least" is controverted by the term "about" which implies that values above and below 65% norfloxacin are permitted. Further, the extent of variance permitted by "about" is unclear in the context. Thus the interpretation of the phrase "at least" in this context is unclear as no definitive minimum can be defined.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by KATDARE et al. (US 4,639,458).

10. KATDARE discloses a direct compression quinoline carboxylic acid tablet utilizing non-hydrated quinoline carboxylic acid. See col 1 lines 1-5. The tablet in KATDARE comprises norfloxacin and minimal amounts of other processing aids with no water added. See col 1 lines 58-60. The tablet formulation contains less than 2% water, see col 2 line 20. The processing aids include a disintegrant, a filler/binder and a lubricant See col 1 lines 53-63. Specifically, the filler is microcrystalline cellulose (13-18.5%) the lubricant is magnesium stearate (0.5-2%) and the disintegrant is croscarmellose sodium (1-4.5%). The tablet can be coated by conventional means, see col 1 lines 64-66.

11. Instant Claims 1, 3-9 and 11-13 require a quinoline carboxylic acid and either an inorganic or organic acid. The instant claims do not prohibit the active from being its own acid. Therefore, norfloxacin, which is both a quinoline carboxylic acid and an organic acid, anticipates the instant claims.

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12. Claims 1, 3-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by ANZAGHI et al. (WO 02/39992).

13. ANZAGHI discloses quinolonic antibacterial agents for use in oral pharmaceutical compositions. The quinolonic antibacterial agents are between 40 and 80% by weight of the total adduct. See claims 1 and 4. The quinolonic agent adduct can be filtered, spraydried giving a powder form and with the addition of suitable excipients used as granules or tablets. See example 1, claim 16 and claim 17. The quinolonic agent can further be norfloxacin, see claim 7 and example 1. In example 1, ANZAGHI also combines the quinolone agent with an inorganic acid, hydrochloric acid.

14. Therefore, instant claims 1, 3-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over KATDARE et al. (US 4,639,458) in view of STORM et al. (US 7,250,176).

19. KATDARE is described above. KATDARE does not describe the use of anhydrous citric acid as a stabilizer or the use of sodium starch glycollate as a disintegrant. However, KATDARE does suggest or motivate the use of processing aids, see col 3 lines 58-60.

20. STORM describes using a high dose of amoxicillin in a tablet form to treat bacterial infections. STORM also describes an immediate release form consisting of a coating or bilayer and a core formed by wet or dry granulation. The immediate release layer is described as a disintegrant and specifically contains sodium starch glycollate. See col 12 lines 48-63, example 1, 4 and 5. Anhydrous citric acid is disclosed in claims 23, 37, 106, 131 for use in tablet formulations, for example granules, see example 5.

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Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the disintegrant and organic acid of STORM with the antibacterial agent of KATDARE, resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a



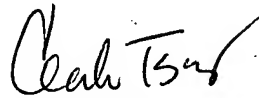
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/TJM/



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